Initial Approval: January 8, 2020

CRITERIA FOR PRIOR AUTHORIZATION

Minimum Requirements Prior Authorization

BILLING CODE TYPE For drug coverage and provider type information, see the KMAP Reference Codes webpage.

MANUAL GUIDELINES Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in Table 1 below.

GENERAL CRITERIA FOR INITIAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must be approved for the indication, age, and not exceed dosing limits listed in Table 1.
- Certain indications are considered non-essential and are not covered. These are also listed in Table 1.
- For all agents listed, the preferred PDL drug, if applicable, which treats the PA indication, is required unless the patient meets the non-preferred PDL PA criteria.

CRITERIA FOR RENEWAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must not exceed age and dosing limits listed in Table 1.

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months

Table 1. FDA-approved indication, age, and dosing limits.

Medication	Indication(s)	Age	Dosing Limits	Provider Specialty
CFTR Modulators				
Elexacaftor/tezacaftor/ivacaftor (Trikafta)	Cystic fibrosis with ≥1 *F508del* mutation	≥ 12 years	200mg/100mg/300mg total per day.	N/A
Ivacaftor (Kalydeco)	Cystic fibrosis with ≥1 CFTR gene mutation that is responsive to ivacaftor based on clinical and/or in vitro assay	≥ 6 months	300mg total per day.	N/A
Lumacaftor/ivacaftor (Orkambi)	Cystic fibrosis with homozygous *F508del* mutation	≥ 2 years	800mg/500mg total per day.	N/A
Tezacaftor/ivacaftor (Symdeko)	Cystic fibrosis with homozygous *F508del* mutation or ≥1 CFTR gene mutation that is responsive to tezacaftor/ivacaftor based on clinical and/or in vitro assay	≥ 6 years	100mg/300mg total per day.	N/A

References

1. Trikafta (elexacaftor/tezacaftor/ivacaftor) [package insert]. Boston, MA: Vertex Pharmaceuticals Inc.; October 2019.
2. Kalydeco (ivacaftor) [package insert]. Boston, MA: Vertex Pharmaceuticals Inc.; April 2019.
3. Orkambi (lumacaftor/ivacaftor) [package insert]. Boston, MA: Vertex Pharmaceuticals Inc.; July 2019.
4. Symdeko (tezacaftor/ivacaftor) [package insert]. Boston, MA: Vertex Pharmaceuticals Inc.; June 2019.

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DRUG UTILIZATION REVIEW COMMITTEE CHAIR

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DATE

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PHARMACY PROGRAM MANAGER
DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

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DATE